



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,571	09/04/2003	John A. Sazy	101896-706 (DEP-128CON)	6429
21125 7590 09/18/2008 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604				
EXAMINER PELLEGRINO, BRIAN E				
ART UNIT		PAPER NUMBER		
3738				
NOTIFICATION DATE		DELIVERY MODE		
09/18/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

doctet@nutter.com



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/655,571
Filing Date: September 04, 2003
Appellant(s): SAZY, JOHN A.

Ronald Cahill
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 6/24/08 appealing from the Office action mailed 11/20/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: The Examiner made an alternative rejection of claim 30 under 35 U.S.C. 102/ 35 U.S.C. 103(a) over Schafer (6143032). The Appellant stated the claim was rejected under 35 U.S.C. 102 (e) as anticipated by Schafer '032. Thus, Appellant incorrectly stated claim 30 was rejected solely under 102.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,143,032	Schafer et al.	11-2000
4,820,305	Harms et al.	4-1989
5,702,449	McKay	12-1997
6,302,914	Michelson	10-2001
4,904,261	Dove et al.	2-1990
6,231,615	Preissman	5-2001
5,062,850	MacMillan et al.	11-1991

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1,3,5,6,13,14,19,28 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Schafer et al. (6143032). Fig. 3 shows a unitary body that is banana-shaped as viewed from above. Fig.2 illustrates the body has openings evenly spaced about the circumference. Schafer discloses the body has a continuous front arc and a continuous back arc with two radiuses of curvature either equal or different, col. 2, lines 26-32. Schafer also discloses the implant body can be made of a metal or polymer, col. 3, lines 14,15. According to Figs. 1 and 3, it can be construed that the width is greater than the length.

Claim 30 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schafer et al. It would have been obvious to one of ordinary skill in the art to modify the ratio of length to width to have a width at least 2.4 times greater the length for Schafer's implant since such a

modification only involves routine skill in the art and would be considered by surgeons as they treat patients of various sizes, for example children would have smaller dimensions as opposed to adults requiring a much larger cage.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al. '032 in view of Harms et al. '305. Schafer et al. is explained supra. However, Schafer fails to teach the openings are parallelograms or rhombuses. Harms et al. show (Fig. 4) rhombus or parallelogram shaped openings (col. 2, lines 15,16) which allow bone cement to be placed through the openings. It would have been obvious to one of ordinary skill in the art to modify the shape of the openings and use parallelograms or rhombuses as taught by Harms with the implant of Schafer such that they provide a greater surface area to bond to.

Claims 15-18,20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al. '032 in view of Dove et al. '261. Schafer et al. is explained supra. However, Schafer et al. fail to disclose the types of metals or polymers for the prosthesis is made from a carbon-fiber reinforced plastic or a resorbable polymer or stainless steel. Dove et al. teach that the spinal implant can be made from a variety of materials, such as carbon fiber reinforced polymers or stainless steel or biodegradable material, col. 1, lines 46-51. It would have been obvious to one of ordinary skill in the art to use alternative materials as taught by Dove et al. for the implant of Schafer et al. such that it can provide a lighter implant or a more radiopaque implant or one that degrades as tissue ingrowth occurs.

Claims 24,25,31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al. '032 in view of Michelson (6302914). Schafer et al. is explained above. However, Schafer et al. fail to disclose the implant's width or length. Michelson (Fig. 18) shows a spinal cage for supporting the vertebrae. Michelson also teaches that the height and width of the implant correspond to the area that a disc may have been removed, col. 7, lines 47-56. It would have been obvious to one of ordinary skill in the art to use an implant with a width falling within the range of 24-28mm and a length of about 10mm as taught by Michelson for the implant of Schafer et al. such that it can provide the proper dimensions of the patients intervertebral space and support adjacent vertebrae.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al. '032 in view of Dove et al. '261 as applied to claim 20 above, and further in view of MacMillan et al. (5062850). Schafer et al. in view of Dove et al. is explained supra. However, Schafer as modified by Dove fail to disclose the use of polyglycolic acid for the spinal support device. MacMillan et al. teach the use of polyglycolic acid for the vertebral prosthesis because it slowly degrades, col. 6, lines 5-10. It would have been obvious to one of ordinary skill in the art to use polyglycolic acid as the implant material as taught by MacMillan et al. for the vertebral implant of Schafer et al. as modified by Dove et al. such that it degrades slowly to provide space for bone ingrowth.

Claims 22,23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al. '032 in view of Preissman (6231615). Schafer et al. is explained supra. However, Schafer fails to disclose the use of an antibiotic with the polymer or plastic.

Preissman teaches the use of injectable PMMA and the use of an antibiotic, col. 4, lines 2-10. Preissman also teaches the injectable PMMA is used in treating pain in vertebral compression fractures, col. 3, lines 65-67. It would have been obvious to one of ordinary skill in the art to inject polymethylmethacrylate with an antibiotic as taught by Preissman with the vertebral implant of Schafer et al. such that it enhances the treatment given to the patient to reduce infection and provides an efficient way to deliver a cement to aid in fixation and an antibiotic to the treatment site.

Claims 26,27,29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer et al. '032 in view of McKay '449. Schafer et al. is explained supra. However, Schafer fails to teach the height to be about 10mm or the thickness of front arc of the implant to be about 1.5-2mm or the upper and lower edges of the implant formed with smoothly-sloping surfaces in a serpentine arrangement. McKay teaches (Fig. 3) a mesh type implant with the upper and lower surfaces having smoothly-sloping serpentine structure for engagement with the vertebrae. McKay additionally teaches that the serpentine upper and lower edges are for attaching of affixing to the vertebrae, col. 6, lines 24,25. McKay teaches (Fig. 5) a spinal implant and that the thickness of a front arc can be "about 1mm". McKay also teaches (col. 6, lines 38-40, 53,54) the thickness is sufficient to support the vertebrae and not break. The Examiner is interpreting "about 1.5mm" to be "about 1mm". It would have been obvious to one of ordinary skill in the art to use a thickness for the arc of the implant of "about 1.5mm" as taught by McKay for the implant of Schafer such that it provides a durable support for the vertebrae that can withstand compressible loads. McKay also teaches the height of the implant to be

10mm, col. 6, line 36. It would have been obvious to one of ordinary skill in the art to use the teaching of providing a spinal cage with a height of 10mm as taught by McKay for the implant of Schafer such that it provides enough space between the vertebrae and approximates the natural disc space, col. 2, lines 62,63 of McKay. The use of a serpentine arrangement for affixing the implant to the vertebrae is well known in the art and would have been obvious to one of ordinary skill to incorporate the smoothly-sloping serpentine arrangement as taught by McKay with the cage of Schafer such that the implant does not move between the vertebrae once implanted.

(10) Response to Argument

Appellant argues that the claimed invention being "banana-shaped" is different than a kidney shaped prosthesis. However, the Examiner respectfully disagrees because not all banana and kidney shapes are necessarily different as Appellant alleges. It appears Appellant failed to appreciate the fact that bananas have a variety of different shapes. Appellant presents a definition (page 8 of Brief) for the first time that is *not in the specification* that a banana is an elongate, often curved fruit that can be yellow. However, there are other types of bananas as the Examiner already informed the Appellant such that the use of banana-shape is broad and can be interpreted with respect to the many types of bananas known to exist. Appellant then admits there are different banana shapes, but argues that "banana-shape" is considered different than a kidney shape, page 9 of Brief. While Appellant's opinion disputes the two elements used as a reference to describe a shape are not similar, the Examiner can consider some bananas or a structure similar to a banana to have a shape similar to

what Appellant's claimed invention is defined as since the only structural feature defining the shape of a banana in Claim 1 is that it *has two radius of curvatures*. *Both a banana and a kidney are known to have two radius of curvatures* and thus this further supports the fact that kidney and banana shapes can be similar. Thus, the banana-shape claimed invention as defined by a curvature in the walls, is clearly seen in the drawing (Fig. 3) of Schafer as seen from above. Appellant argues that claim 30 is not met by Schafer since the reference does not state the width is greater by 2.4 than the length. First it should be mentioned that claim 1 states the "banana shape" is defined by a view from above. Since this is a broad and undefined limitation, it does not give much perspective other than someone would viewing an object from above would visualize a banana shaped object as having somewhat of an elongate shape and a width usually less than the length. However, in claim 30, Appellant being their own lexicographer defines the "width" as the greater dimension or presents a different reference frame. Since Schafer has the same shape as Appellant and shows that the dimension Appellant nominally calls the width as being greater than the length dimension, it can be seen there is a difference in dimension of clearly greater than two times. However, as mentioned above in the Examiner's rejection- Schafer did not explicitly state the dimension being 2.4 times, but Schafer did state the dimension can be altered to change the radius and thus this can be interpreted as to lengthen the arc, see col. 2, lines 28-31. Appellant argues one of ordinary skill would not modify the shape since claim 30 is said to have nothing to do with size, (Appellant's Brief, page13). Appellant is mistaken, since length and width are clearly size limitations and Schafer's

Art Unit: 3738

cage would have obviously had a change in shape if one were to modify size (length or width dimensions) to change the radius of curvature as suggested by Schafer.

Appellant then argues the rejections of Schafer in view of Michelson are not obvious stating the device of Michelson is designed to be used differently. The key issue is size dimensions of which Appellant arbitrarily names dimensions contradictory to what someone of ordinary skill would consider to be. The claims do not set forth any reference frames as to which direction a dimension has to be established, thus the prior art can nominally have dimensions used the same way Appellant has and the Examiner used the teachings of the prior art according to Appellant's use of dimensions.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Brian E Pellegrino/

Primary Examiner, Art Unit 3738

Conferees:

/Corrine M McDermott/

Supervisory Patent Examiner, Art Unit 3738

/Thomas Barrett/

TQAS TC3700